IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Mark Korsten
Application No. 10/672,241
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For: COMPOSITIONS AND METHODS FOR BOWEL CARE IN INDIVIDUALS WITH CHRONIC INTESTINAL PSEUDO-OBSTRUCTION
Examiner: Jennifer M. Kim
Art Unit: 1614
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AMENDMENT AND RESPONSE TO RESTRICTION REQUIREMENT

This Amendment and Response to Restriction Requirement ("Amendment") is filed in answer to the non-final Office action, dated November 24, 2006. A one-month period for response was set by the Office action; thus, this Amendment is timely filed on or before December 24, 2006. The Commissioner is authorized to charge any fees that may be required in connection with this filing to Deposit Account No. 02-4550.

Please amend the claims as set forth beginning on page 2.

Remarks are on page 6 of this Amendment.

EXHIBIT A

LISTING OF CLAIMS

The following listing of claims will replace all prior versions and listings of claims in the application:

1. **(Original)** A method of bowel care, comprising:

chronically administering a therapeutically effective amount of a drug combination comprising an acetylcholinesterase inhibitor and an anti-cholinergic agent to a subject having chronic intestinal pseudo-obstruction.

2. **(Original)** The method of claim 1, wherein the acetylcholinesterase inhibitor is neostigmine, physostigmine, ambenonium, pyridostigmine, edrophonium, demecarium, echothiophate, or pralidoxime.

3. **(Original)** The method of claim 2, wherein the acetylcholinesterase inhibitor is neostigmine.

4. **(Original)** The method of claim 1, wherein the anti-cholinergic agent is glycopyrrolate, atropine, methscopolamine, homatropine, methantheline, propantheline, anisotropine, clidinium, hexocyclium, isopropamide, mepenzolate, oxyphenonium, or tridihexethyl.

5. **(Original)** The method of claim 4, wherein the anti-cholinergic agent is glycopyrrolate.

6. **(Original)** The method of claim 1, wherein the acetylcholinesterase inhibitor is neostigmine and the anti-cholinergic agent is glycopyrrolate.

7. **(Original)** The method of claim 6, wherein the therapeutically effective amount of the drug combination is about 1 mg to about 2 mg neostigmine and about 0.2 mg to about 0.4 mg glycopyrrolate.

8. **(Original)** The method of claim 6, wherein the therapeutically effective amount of the drug combination is a ratio of neostigmine to glycopyrrolate of about 2.5:1 to about 10:1 by weight.

9. **(Original)** The method of claim 8, wherein the therapeutically effective amount of the drug combination is a ratio of neostigmine to glycopyrrolate of about 5:1 by weight.

10. **(Original)** The method of claim 1, wherein the chronic intestinal pseudo-obstruction is an effect of spinal cord injury, amyotrophic lateral sclerosis, spina bifida, multiple sclerosis, Parkinson's disease or dementia.

11. **(Original)** The method of claim 10, wherein the chronic intestinal pseudo-obstruction is an effect of spinal cord injury.

12. **(Original)** The method of claim 11, wherein the chronic intestinal pseudo-obstruction is an effect of paraplegia or quadriplegia.

13. **(Original)** The method of claim 1, wherein the acetylcholinesterase inhibitor and the anti-cholinergic agent are administered at about the same time.

14. **(Original)** The method of claim1, wherein the anti-cholinergic agent is administered about 1 to about 10 minutes after the acetylcholinesterase inhibitor.

15. **(Original)** The method of claim 1, wherein the method of administration of the acetylcholinesterase inhibitor is intramuscular injection, intravenous injection, rectal suppository, transnasal spray, sublingual tablets, or sublingual drops.

16. **(Original)** The method of claim 1, wherein the method of administration of the anti-cholinergic agent is intramuscular injection, intravenous injection, rectal suppository, transnasal spray, sublingual tablets, or sublingual drops.

17. (**Original**) The method of claim 1, wherein the acetylcholinesterase inhibitor and the anti-cholinergic agent are administered by the same method of administration.

18. (**Original**) The method of claim 17, wherein the method of administration is intramuscular injection, intravenous injection, rectal suppository, transnasal spray, sublingual tablets, or sublingual drops.

19. (**Original**) The method of claim 18, wherein the method of administration is intramuscular injection or intravenous injection.

20. (**Original**) The method of claim 1, wherein the chronic administration occurs at least one time per week over a period of at least one month.

21. (**Original**) The method of claim 20, wherein the chronic administration occurs over a period of at least six months.

22. (**Original**) The method of claim 1, wherein the chronic administration occurs at least three times per week over a period of at least one month.

23. (**Original**) A method of bowel care for a subject comprising:

identifying a subject having chronic intestinal pseudo-obstruction as an effect of spinal cord injury; and

co-administering to the subject a therapeutically effective amount of a drug combination comprising about 1 mg to about 2 mg of neostigmine and about 0.2 mg to about 0.4 mg glycopyrrolate.

24. (**Original**) The method of claim 23, wherein the drug combination is chronically co-administered at least one time per week for at least one month.

25. (**Original**) The method of claim 24, wherein the drug combination is chronically co-administered at least three times per week.

26. **(Original)** The method of claim 24, wherein the drug combination is chronically co-administered for at least six months.

27-31. **(Canceled)**.

REMARKS

Claims 1-31 were pending in this application. Claims 27-31 are canceled without prejudice as directed to non-elected subject matter. Applicant reserves the right to pursue all canceled subject matter in one or more continuing applications. After entry of this Amendment, **claims 1-26 are pending in this application**.

The Office contends that the pending claims are directed to two "distinct" inventions and has required restriction to one alleged invention under 35 U.S.C. §121. The two Groups provided by the Office are:

Group I (claim 27-31)	drawn to a pharmaceutical composition comprising a therapeutically effective amount of a drug combination comprising neostigmine and glycopyrrolate in a weight ratio of neostigmine to glycopyrrolate of about 2.5:1 to about 10:1; and
Group II (claim 1-26)	drawn to a method of bowel care, comprising chronically administering a therapeutically effective amount of a drug combination comprising an acetylcholinesterase inhibitor and an anti-cholinergic agent to a subject having a chronic intestinal pseudo-obstruction.

For prosecution in the present application, Applicant elects the alleged invention of Group II (claims 1-26). The claims have been amended in conformance with this election.

Substantive examination of the pending claims is respectfully requested. The Examiner is invited to call the undersigned if the Examiner believes that a telephone interview would facilitate substantive examination of this application.

Respectfully submitted,

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